FDA 510(k) Premarket Notification

CLEARED

K243713 Single Use RF Surgical Electrode (Needle Type) (AN-B, AN-C, AN-E, AN-I, AN-S, AN-W3A, AN-F3A, AN-IL, AN-SL, AN-W3B, AN-F1A, AN-F3B, AN-B3A)

Aug 19, 2025
260 days to decision

K243713 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 2, 2024
Decision date	Aug 19, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Agnes Medical Co., Ltd.**
Location	Seongnam-Si, KR
Contact	Heui Kyeong Pak
510(k) history	7 submissions · 7 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**E & M**
Contact	Sanghwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov